UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JILL WHITCOMB
1442 Oriole Drive
Hartford, WI 53027

Plaintiff,

v. Case No. 13-C-990

KATHLEEN SEBELIUS in her official capacity
as Secretary, United States Department
of Health and Human Services,
615-F Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201,

Defendant.

FIRST AMENDED COMPLAINT

Plaintiff, Jill Whitcomb, by her undersigned counsel, brings this action for judicial review of final agency decisions of Defendant Kathleen Sebelius, in her official capacity as Secretary of the United States Department of Health and Human Services, and states as follows:

PRELIMINARY STATEMENT

1. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§1395 *et seq.* ("the Medicare Act"), and the Administrative Procedure Act ("APA"), 5 U.S.C. §§551 *et seq.* Plaintiff, Jill Whitcomb, seeks judicial review of a final decision of Defendant, the Secretary ("the Secretary") of the Department of Health and Human Services ("HHS"), denying Medicare payment for claims relating to a continuous glucose monitor.

2. Ms. Whitcomb has had Type I diabetes for 35 years, which despite being consistently conscientious following nutritional instructions, regularly exercising, performing frequent self-monitoring (6 or more times daily), and following a comprehensive insulin administration regimen for her diabetes, her glucose levels still remain uncontrolled, i.e., "brittle."

3. Continuous glucose monitoring is the standard of care for brittle diabetics.

4. A National Coverage Determination ("NCD") is a determination regarding coverage that exists nationally. NCD 40.2 provides Medicare coverage for home blood glucose monitors for diabetics who are Medicare beneficiaries.

5. In 2008, National Government Services ("NGS") issued a local coverage determination ("LCD") L27231, indicating that blood glucose monitors and related accessories and supplies, would be covered when (1) a patient had diabetes which was being treated by a physician; (2) the patient's physician states the patient is capable of using the device; and (3) the device is designed for home use rather than clinical use.

6. The NGS LCD did not indicate that CGM was not covered.

7. However, an NGS informal communication known as an "Article" stated that NGS considers CGM to be "precautionary."

8. Medicare Advantage Organizations ("MAOs") are required to cover at least those medical devices and supplies covered by Medicare.

9. Consistent with the determination of most commercial insurance companies, UnitedHealth of Wisconsin, Inc., issued a policy indicating that it generally covers continuous glucose monitors, deeming them to be reasonable and medically necessary for "brittle" diabetics.

10. The denial at issue in this action first arose when the Secretary, acting through a Medicare Advantage Organization, United Healthcare of Wisconsin/Secure Horizons, unlawfully denied claims for payment from Medicare for the continuous glucose monitor.

11. Ms. Whitcomb appealed these denials through the multi-step Medicare Part B appeals process.

12. After a hearing, Administrative Law Judge Richard Bush found that coverage was consistent with the relevant NCD and LCD, deemed the CGM to be reasonable and medically necessary, and ordered United Healthcare to cover the CGM for Ms. Whitcomb. The ALJ specifically declined to follow the informal Article noting the various emergency visits, hospital records and other medical records supported her need for CGM.

13. The MAO appealed and the Secretary reversed the ALJ's decision and denied the CGM claims at issue on the grounds that "the record was insufficient to depart from the coverage standards in the LCD and policy article," and stated CGM is not covered by Medicare.

14. The exhaustion of the Medicare appeals process took over 18 months and has resulted in an inconsistent and unsupported decision by the Medicare Appeals Council ("MAC"), which is the Secretary's final decision for purposes of judicial review.

15. Plaintiff seeks an order reversing these payment denials and instructing the Secretary to pay the claims at issue in accordance with applicable law. The decision at issue is arbitrary and capricious, not supported by the evidence or Medicare law, regulation or guidance, and is inconsistent with the medical records and the standard of care.

Jurisdiction and Venue

16. The Court has subject matter jurisdiction under 42 U.S.C. §§405(g) and 1395ff(b) (appeal of final Medicare program agency decision) and under 28 U.S.C. §§1331 (federal question) and 1361 (mandamus).

17. Venue lies in this judicial district under 42 U.S.C. §§405(g) and 1395ff(b) and 28 U.S.C. §1391(e).

Parties

18. Jill Whitcomb is a Medicare beneficiary residing at 1442 Oriole Drive, Hartford, WI 53027 who is seeking Medicare coverage of her claims for CGM.

19. Ms. Whitcomb has been a Medicare beneficiary since July 1, 2007.

20. Plaintiff brings this action, which is an appeal of the Secretary's final decision denying Medicare claims for CGM.

21. Defendant Kathleen Sebelius is the Secretary of HHS, the federal department which contains the Centers for Medicare & Medicaid Services ("CMS"). The Secretary, the federal official responsible for administering the Medicare Program, has delegated that responsibility to CMS.

Factual Background

A. General Background of the Medicare Program

22. The Medicare Act establishes a program of health insurance for the aged, disabled, and individuals afflicted with end-stage renal disease. 42 U.S.C. §§1395 -1395ccc; 42 C.F.R. Parts 400 – 1004. Medicare includes Parts A through D. This action arises under Part B (covering basic non-hospital medical needs) and Part C (relating to Medicare Advantage Organizations).

23. Under 42 U.S.C. §1395hh(a)(1), the Secretary is required to "prescribe such regulations as may be necessary to carry out the administration" of the Medicare program. That statute also states:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1). U.S.C. §1395hh(a)(2).

24. The Secretary has elected to publish many rules implementing the Medicare program in various manuals, such as the Medicare Program Integrity Manual ("MPIM") and the Medicare Claims Processing Manual ("MCPM"). However, under 42 U.S.C. §1395hh(a)(2), these manual provisions, which are not promulgated in accordance with the notice and comment provisions of the APA, are not effective to the extent that any of them "establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" under Medicare.

B. <u>Medicare Coverage and Payment of DMEPOS</u>

25. Medicare Part B provides for coverage and payment for "medical and other health services," which includes durable medical equipment prosthetics, orthotics and supplies ("DMEPOS") provided to Medicare beneficiaries. 42 U.S.C. §§1395k(a) and 1395x(n) and (s). To be paid by Medicare, medical devices and supplies must be found to be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. §1395y(a).

26. DMEPOS is categorized by CMS pursuant to the Healthcare Common Procedure Coding System ("HCPCS") and is assigned an alpha-numeric code consisting of a letter and a

four-digit number. Some items of DMEPOS are assigned a unique HCPCS code. To obtain a unique code, a medical device or supply must achieve sufficient volume, *i.e.*, adoption within the medical community. *See* www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/decisiontree.pdf.

27. Claims for Medicare payment for DMEPOS items supplied to Medicare beneficiaries are presented to DME Medicare Administrative Contractors ("DMACs"). DMACs adjudicate these claims as agents of the Secretary pursuant to contracts with him. The country is divided into four geographic jurisdictions, each of which has its own DMAC. A DMEPOS supplier must submit each of its claims to the DMAC having jurisdiction for reimbursement of that claim. 42 C.F.R. §424.32.

28. After a claim has been submitted to the appropriate DMAC, the DMAC must determine if the item is covered or otherwise reimbursable under the Medicare Act, determine any payment due and make that payment accordingly, and notify the parties of the determination. 42 C.F.R. §405.920. For DMEPOS, payment is 80% of the actual charge or a fee schedule amount where a fee schedule has been created in accordance with 42 C.F.R. §§ 414.220 through 414.232. *See* 42 C.F.R §414.210.

C. <u>Medicare Coverage and Glucose Monitoring</u>

29. A National Coverage Determination ("NCD") is "a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. §405.1060(a)(1).

30. An NCD is binding on all Medicare contractors, including administrative law judges ("ALJs") and the Medicare Appeals Council ("AC"). 42 C.F.R. §405.1060(a)(4).

31. To ensure coverage of diabetic testing equipment and supplies, in 2006, the Secretary issued the current effective version of the NCD providing Medicare coverage for blood

glucose monitors. See Medicare National Coverage Determinations Manual §40.2, Home Blood Glucose Monitors (hereinafter "NCD 40.2").

32. Under NCD 40.2, a home blood glucose monitor is covered when:

a. The patient has been diagnosed as having diabetes;

b. The patient's physician states that that the patient is capable of being trained to use the particular device prescribed in an appropriate manner; and

c. The device is designed for home rather than clinical use. Id.

33. The NCD does not distinguish between single use home glucose monitors or continuous use glucose monitors.

34. In addition to an NCD, MACs, including DMACs, can issue local coverage determinations ("LCDs").

35. LCDs are issued after consideration of the peer-reviewed literature, consultation with the relevant medical community, notice and comment. See Medicare Program Integrity Manual ("MPIM") Ch. 13, §13.7.

36. When the ALJ is rendering a decision, although not bound by an LCD, an ALJ must give deference to an LCD. 42 C.F.R. §405.1062. If an ALJ does not give deference to an LCD, the ALJ must explain why he or she did not.

37. In 2008, National Government Services ("NGS") issued LCD L27231 indicating that blood glucose monitors and related accessories and supplies, would be covered when (1) a patient had diabetes which was being treated by a physician; (2) the patient's physician states the patient is capable of using the device; and (3) the device is designed for home use rather than clinical use.

38. The NGS LCD did and does not indicate that CGM was and is not covered.

39. Articles, which are informal communications issued by MACs, may be issued without consultation with the relevant medical community or the peer reviewed literature, are not subject to challenge by providers or beneficiaries, and are not entitled to any deference by either the QIC or ALJ. 42 C.F.R. §405.1062.

40. Medicare Advantage Organizations ("MAOs) are required to offer their enrollees, at a minimum, all basic Medicare covered services. See 42 C.F.R. §422.101.

41. MAOs must comply with NCDs and LCDs. Id.

42. The UnitedHealthcare/Secure Horizons Evidence of Coverage document explicitly states that is covers diabetes self-monitoring training, nutrition therapy, and supplies, including "coverage for glucose monitors." See A.R. 802.

D. <u>The Process for Appeals of Medicare Claims Decisions</u>

43. Congress has established a five-step process for a Medicare beneficiary, such as Ms. Whitcomb, to follow to obtain judicial review when she is dissatisfied with the initial determination of a claim by the DMAC. The first step in the process is request for redetermination by the DMAC. *See* 42 C.F.R. §§405.940 through 405.958.

44. Upon a request for redetermination, the DMAC is required to adjudicate a claim and render a decision based on the evidence in the record. 42 C.F.R. §405.954. Under 42 C.F.R. §405.956(b), the redetermination notice issued by the DMAC must include, *inter alia*, a summary of the evidence used in making the redetermination; an explanation of relevant laws, regulations, coverage rules, CMS policies that apply to the case; and a summary of the rationale for the redetermination in clear, understandable language. 42 C.F.R. §405.956(b).

45. A Medicare beneficiary who is dissatisfied with a DMAC's redetermination decision may request reconsideration by the DME qualified independent contractor ("QIC"). 42

C.F.R. §405.960. The QIC is required to review the record of the claims and issue a reconsideration decision having the same decision elements as the DMAC's redetermination decision. 42 C.F.R. §405.976(b).

46. A Medicare beneficiary may appeal the QIC reconsideration decision by requesting a hearing before an Administrative Law Judge ("ALJ"). 42 C.F.R. §405.1000.

47. ALJs are bound to follow an NCD. 42 C.F.R. §405.1060(a)(4).

48. In contrast to an NCD, local coverage determinations ("LCDs") issued by MACs, including DMACs, are not binding on an ALJ. 42 C.F.R. §405.1062(a).

49. When the ALJ is rendering a decision, although not bound by an LCD, if an ALJ applies an LCD, the ALJ must apply the LCD in place on the date the item or service was provided. 42 C.F.R. §405.1034.

50. Articles, which are informal communications issued by MACs, may be issued without consultation with the relevant medical community, are not subject to challenge by providers or beneficiaries, and are not entitled to any deference by either the QIC or ALJ. 42 C.F.R. §405.1062.

51. After an ALJ issues a decision, the Medicare Appeals Council ("AC") may decide on its own motion to review a decision by an ALJ. See 42 C.F.R. §405.1110. An MAO also may appeal a case to the AC for it to consider reviewing.

52. An NCD is binding on the AC and the AC limits its review to the evidence contained in the record before the ALJ. 42 C.F.R §405.1122(a)(1).

53. The AC's decision becomes the Secretary's decision and is the final agency decision for purposes of judicial review. 42 C.F.R. §405.1136(d).

54. A Medicare beneficiary seeking judicial review of the Secretary's final decision may file a complaint "in the district court of the United States for the judicial district in which the party resides or where such individual, institution, or agency has its principal place of business." 42 C.F.R. §405.1136; *see also* 42 U.S.C. §§405(g) and 1395ff(b). Timely judicial review is being sought for a decision rendered by the Secretary. 42 C.F.R. §405.1130 and §405.1134.

STATEMENT OF FACTS AND PRIOR PROCEEDINGS

A. Continuous Glucose Monitoring and Brittle Diabetics

55. Unfortunately, despite consistently conscientiously following nutritional instructions, regularly exercising, performing frequent self-monitoring (six or more times daily), and following a comprehensive insulin administration regimen for their diabetes, some individuals still have uncontrolled glucose levels. Such diabetics are known as "brittle diabetics."

56. Such individuals suffer from hypoglycemic unawareness, i.e., they are unaware of an impending, dangerous low drop in blood glucose. Hypoglycemic unawareness may result in prolonged and profound exposure to hypoglycemia, resulting in seizure, loss of consciousness and brain damage.

57. Further, brittle diabetics often have frequent nighttime hypoglycemic episodes which causes a progressive loss of mental function.

58. CGM alerts brittle diabetics of both hypo- and hyperglycemic episodes which can occur at a frequency that would confound any attempt to manage through simple finger blood glucose checks.

59. CGM operates by measuring the interstitial fluid under the skin which consistently tracks with and reflects the glucose concentration in the blood.

60. CGM has been recognized as the standard of care for brittle diabetics not only within the United States, but internationally. See the consensus statements/guidelines of the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring, at 3 (which has recommended CGM since at least 2007); the American Diabetes Association at S21-S22 (which has included it in its recommendation since at least 2009); the Endocrine Society at 4, 13; the German Diabetes Association (which reviews the favorable consensus statements of many European nations); various French Endocrinology and Diabetic Societies at S76-77; the European Society for Pediatric Endocrinology, the Pediatric Endocrine Society and the International Society for Pediatric and Adolescent Diabetes at 4-5, 11.

61. The consensus of medical opinion on the safety and effectiveness of CGM for brittle diabetics is supported by at least nine peer-reviewed publications reflecting randomized, controlled clinical trials. See Attachment 1 hereto.

62. Based on the consensus statements, peer-reviewed literature and widespread acceptance of CGM for brittle diabetics, more than 95% of commercial insurers cover CGM.

63. A federally funded technology assessment found CGM reasonable and medically necessary for brittle diabetics. See the Agency for Health Care Research and Quality ("AHRQ") report of 2010 (AHRQ at 102-103, 105).

B. <u>The Proceedings Below Relating to the Claims at Issue in this Action</u>

64. This is an action for judicial review of final administrative decision of the Secretary with the AC Appeal Number 1-1012671541, M-13-2509 (issued August 23, 2013).

65. Ms. Whitcomb has had Type 1 diabetes for 35 years.

66. Despite frequent testing (an average of 10 times daily), she was unable to gain control of her diabetes and has been forced into disability. She also suffers from hypoglycemia unawareness and gastroparesis.

67. Because of her hypoglycemia, Ms. Whitcomb repeatedly has lost consciousness, has been hospitalized and has been taken to the emergency room. See, e.g., A.R. 835.

68. Accordingly, on April 14, 2011, her healthcare provider prescribed her a continuous glucose monitor which checks Ms. Whitcomb's glucose approximately 288 times a day and alerts her when she is experiencing a hypoglycemic event. See A.R. 144.

69. Ms. Whitcomb's healthcare provider signed a statement of medical necessity attesting that CGM was and is reasonable and medically necessary for Ms. Whitcomb. See A.R. 146.

70. With CGM, Ms. Whitcomb had a "vast" clinical improvement of her blood glucose level control. In the first month of using the CGM, she experienced only six hypoglycemic events compared to the 22 events in the preceding month when she did not have a CGM.

71. Ms. Whitcomb filed a claim for the CGM and related supplies which were denied by UnitedHealthcare although UnitedHealthcare stated it understood how CGM "might be helpful for [Ms. Whitcomb]."

72. Ms. Whitcomb appealed the denial through the administrative process.

73. Hearings were conducted on October 15, 2012 and January 17, 2013. During the January 17, 2013 hearing, Ms. Whitcomb's healthcare provider noted that if the Article applied, it was inconsistent with the standard of care, the literature that supported CGM, and the dire need of her patient, Ms. Whitcomb.

74. Ms. Whitcomb's healthcare provider noted CGM was "precautionary" solely to the extent that it prevented hypoglycemic and hyperglycemic events and premature death. A.R. at 838, 840 and 847.

75. On February 6, 2013, the Administrative Law Judge Bush rendered a Fully Favorable Decision finding that Medicare coverage of CGM is consistent with the NCD and LCD, and that the CGM was reasonable and medically necessary for Ms. Whitcomb.

76. The ALJ found that neither the NCD nor LCD distinguished continuous glucose monitors and continuous glucose monitors and that Ms. Whitcomb satisfied the coverage criteria of NCD 40.2 an LCD L27231.

77. The ALJ did not give the Article deference because Ms. Whitcomb had demonstrated her dire medical need for CGM based on her uncontrolled diabetes that had resulted in emergency room visits.

78. The ALJ's decision was consistent with the decisions of prior ALJs who had considered this issue for other Medicare beneficiaries.

79. On March 1, 2013, the MAO appealed the favorable ALJ decision to the AC.

80. On August 23, 2013, the AC reversed the Fully Favorable ALJ Decision and found that CGM was not covered.

81. The Secretary indicated that the NCD did not address continuous glucose monitoring and found that "the record was insufficient to depart from the coverage standards in the LCD and policy article."

COUNT I
Violation of APA under 5 U.S.C. §706
(CGM is Not Precautionary and Not Excluded from Coverage)

82. Plaintiff hereby incorporates by reference paragraphs 1 to 64 herein.

83. Under the Medicare statute, 42 C.F.R. §1395ff(b), the final agency decision included in this action is subject to judicial review under the applicable provisions of the APA. Under the APA, the reviewing court shall set aside the final agency decision if, *inter alia*, it is contrary to law, arbitrary and capricious, an abuse of discretion, or unsupported by substantial evidence in the record.

84. To the extent that the Secretary's decision in this action found that CGM is precautionary and therefore not reasonable and medically necessary, the Secretary's decision must be set aside because it is contrary to law, arbitrary, capricious, and unsupported by substantial evidence in the record.

85. CGM is reasonable and necessary for brittle diabetics as widely recognized.

86. Based on the foregoing, the Secretary's decision that the CGM is not covered because it is precautionary, is contrary to Medicare regulations, arbitrary and capricious, and unsupported by substantial evidence in the record, and Plaintiff asks the Court to reverse the Secretary's decisions and issue an order finding that the CGM is not precautionary and is reasonable and medically necessary, and direct the Secretary to make appropriate payment for the device.

COUNT II
Violation of APA under 5 U.S.C. §706
(CGM is Covered Under NCD 40.2)

87. Plaintiff hereby incorporates by reference paragraphs 1 to 69 herein.

88. The Secretary's decision in this action must be set aside because it is arbitrary, capricious, and unsupported by substantial evidence in the record. The finding that CGM is precautionary is not supported by the record and is contrary to the evidence which includes

numerous peer-reviewed studies, professional society statements and practicing physicians and NCD 40.2.

89. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision and issue an order finding that the CGM is reasonable and medically necessary under NCD 40.2.

COUNT III

Violation of APA under 5 U.S.C. §706
(Failure to Follow the NCD)

90. Plaintiff hereby incorporates by reference paragraphs 1 to 72 herein.

91. To the extent that the Secretary's decision is premised on its failure to apply the NCD 40.2, the Secretary's decision must be set aside because it is contrary to law, arbitrary and capricious and without observance of procedure required by law. 42 C.F.R. §405.1060(a)(4).

COUNT IV

Violation of APA under 5 U.S.C. §706
(CGM is Not Non-Covered Under LCD L27231)

92. Plaintiff hereby incorporates by reference paragraphs 1 to 74 herein.

93. The Secretary's decision in this action must be set aside because it is arbitrary, capricious, and unsupported by substantial evidence in the record. The finding that CGM is precautionary is not supported by the record and is contrary to the evidence which includes numerous peer-reviewed studies, professional society statement and practicing physicians.

94. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision and issue an order finding that the CGM is reasonable and medically necessary under LCD L27231.

COUNT V

Violation of APA under 5 U.S.C. §706
(Failure to Follow the LCD)

95. Plaintiff hereby incorporates by reference paragraphs 1 to 77 herein.

96. To the extent that the Secretary's decision is premised on its failure to apply the LCD L27231, the Secretary's decision must be set aside because it is contrary to law, arbitrary and capricious and without observance of procedure required by law. 42 C.F.R. §405.1060(a)(4).

97. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's decision and issue an order finding that the CGM is reasonable and medically necessary under LCD L27231 and directing the Secretary to follow LCD L27231.

COUNT V

Violation of APA under 5 U.S.C. §706
(Deference to the Article)

98. Plaintiff hereby incorporates by reference paragraphs 1 to 79 herein.

99. To the extent that the Secretary's decision is premised on giving deference to an NGS Article, which is not an LCD and is not entitled to deference, the Secretary's decision must be set aside because it is contrary to law, regulation and arbitrary and capricious, and without observance of procedure required by law.

100. The Secretary provided no basis for refusing to give deference to the LCD, the ALJ's rationale for not applying the Article, or acknowledging that even if the Article applied, it should not be given deference to the in view of Ms. Whitcomb's uncontested dire need for CGM to avoid life-endangering glucose swings.

Requested Relief

WHEREFORE, Plaintiff requests:

1. An order setting aside the Secretary's decision that CGM is not covered;
2. An order declaring CGM is eligible for coverage under the NCD 40.2;
3. As order remanding this action to the Secretary with instruction to order coverage of Ms. Whitcomb's CGM and related supplies;
4. An order that this Court will retain jurisdiction over the decisions at issue until the Secretary's payment of the claims at issue has been completed;
5. Legal fees and costs of suit incurred by Plaintiff; and
6. Such other relief as this Court may consider appropriate.

Date: May 6, 2014

Respectfully submitted,

PLEDL & COHN, S.C.
Attorneys for Plaintiff

/s/ Robert Theine Pledl

By: Robert Theine Pledl
1110 N. Old World Third Street - Suite 215
Milwaukee, WI 53203
TEL 414-225-8999
FAX 414-225-8987
Email rtp@pledlcohn.com

PARRISH LAW OFFICES
By: Debra Parrish
615 Washington Road – Suite 200
Pittsburgh, PA 15228
TEL 412-561-6250
FAX 412-561-6253
Email Debbie@dparrishlaw.com
Admission to E.D. Wis. in progress.